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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,218	09/08/2003	Ernst Peter Strecker	12013/56004	1060

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EXAMINER	
WILLSE, DAVID H	

ART UNIT	PAPER NUMBER
3738	

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05/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/656,218	STRECKER, ERNST PETER	
	Examiner	Art Unit	
	Dave Willse	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-36,38,46,49,51-53,56,57 and 59-73* is/are pending in the application.

4a) Of the above claim(s) *60-73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-36, 38, 46, 49, 51-53, 56, 57, and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 60-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 16, 2006. There is no evidence from the original disclosure that the embodiment possessing a double walled sleeve with an internal space containing medication also includes the wrinkled configuration of the elected species, nor is there any discussion as to how such a chamber would be compressed and folded without substantial loss of medication through the openings **48** during the deployment stages of the procedure.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 56 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Regarding claim 56, the wrinkled embodiment having the feature of "prevent[ing] release of the medication when the structure is in the initial state" (claim 56, last two lines) is unsupported by the original disclosure, particularly since one of ordinary skill would have interpreted the folds or wrinkles to be macroscopic rather than microscopic in nature, and "the wrapping material itself does not stretch" (US 6,193,746 B1: column 2, line 35). Regarding claim 57, there is no suggestion of combining the wrinkled embodiment with either prosthesis shown in Figures 5 and 6 and certainly no explanation to the ordinary practitioner as to how a

wrinkled lining would be applied to cover the structure surrounding the branching orifice (US 6,193,746 B1: column 4, lines 36-38, for example) so as to enable the orifice to expand sufficiently and in such a way that neither the structure nor the (less) wrinkled material impedes blood flow.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33-36 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Schwarz, US 5,957,971. The embodiment shown in Figure 2, for example, includes an elongated hollow structure **34** expandable from an initial state of decreased outer diameter during delivery (column 1, lines 27-30; column 2, lines 38-41; column 5, lines 16-27 and 41; etc.) and a wrinkled lining **32** comprising a synthetic polymer (column 3, lines 56-60; column 4, lines 3-5 and 12-29; etc.) interfaced with a medication for delivery to a patient (column 2, lines 24-27; column 4, line 30 et seq.), the lining being relatively more wrinkled when the structure is in the initial state (column 5, lines 31-40). Regarding claim 34, on adjacent turns or wire-like portions of the

framework **34**, surface portions which face one another constitute interior surfaces and are in contact with the lining (Figures 2 and 10). Regarding claim 35: column 2, lines 28-29; column 4, lines 30-32; column 5, lines 61-62; etc. Regarding claim 36: column 3, lines 65-67.

Claims 38, 46, 49, 51-53, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz, US 5,957,971. Regarding claims 38 and 52, a plurality of through holes of diameter no larger than 0.5 μm would have been obvious in order to accommodate controlled rate microcapsules (column 4, lines 48-55) in such a way that the microcapsules themselves (rather than some other barrier in the lining) "control the rate at which the therapeutic substance is provided to the blood stream or the body lumen" (column 4, lines 48-55), and such a diameter range would have led to nothing more than predictable results in that the microcapsules would be prevented from being dislodged from the lining. Regarding claim 46, the elongated hollow structure **34** being woven from metal would have been an obvious variant in view of column 2, lines 38-39; column 6, lines 4-9; and Figure 3. Regarding claim 49, different medications would have been obvious from the drugs listed (column 2, lines 9-11 and 29-33; column 4, lines 15-17 and 45-47; column 6, line 33; etc.) in order to impart multiple effects as indicated for a particular patient. The inner and outer layers as set forth in claim 51 would have been obvious from column 5, lines 13-15; column 6, lines 28-29; and column 3, line 65. Regarding claim 53, different biodegradability rates would have been obvious in order to deliver the drugs at different rates. Regarding claim 59, polymers such as poly-D,L-lactide were common in the art at the time of the present invention and would have been obvious from column 4, lines 27-29, and column 5, lines 61-62, in order to provide a range of mechanical properties, biodegradability rates, and so on.

The Applicant's remarks have been considered. Regarding the election requirement, "the election has been treated as an election without traverse" (Office action of February 2, 2007; page 2, line 3), and nowhere has the election requirement been vacated, explicitly or implicitly, by any Office action in the instant application. Most of the claims referenced by the Applicant were rejected under 35 U.S.C. 112, first paragraph, in the Office action of May 7, 2007; it would have been rather difficult for the examiner to determine which of the claims were to be withdrawn when not one of claims 33-36, 38-46, and 49-57 (in the amendment of March 28, 2007) was readable on *any* originally disclosed embodiment or species, non-elected or otherwise. Regarding claim 56, the examiner fails to see how a macroscopic wrinkling and unwrinkling imparts a closing and opening of openings which are apparently (Figure 8) similar in size to the through holes (no larger than 0.5 μm in diameter), and there is certainly no suggestion or explanation offered in the original disclosure. It is clear from the original disclosure (e.g., US 6,193,746 B1: column 3, lines 9-12) that the openings expand as the prosthesis (and hence the lining) expands (in non-elected species or embodiments), but the wrapping material or lining does not stretch in the wrinkled embodiment (*ibid.*: column 2, line 35).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is 571-272-4762 and who is generally available Monday, Tuesday, and Thursday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Dave Willse/
Primary Examiner
Art Unit 3738